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(71) Applicant and
(72) Inventor: **KAREV, Andrei Vladimirovich** [RU/RU]; pr. Dzhambula, 14-23, St.Petersburg, 191180 (RU).

(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: **PULNEV, Sergei Appolonovich** [RU/RU]; Piskarevsky pr., 16-254, St.Petersburg, 195221 (RU). **RYZHKOV, Vladimir Konstantinovich** [RU/RU]; Angliisky pr., 21/60-29, St.Petersburg, 190121 (RU).

(74) Agents: **RYBAKOV, Vladimir M.** et al.; Agency of Patent Attorneys "ARS-PATENT", Shvedsky per., 2-314, A/ya 230, St.Petersburg, 191186 (RU).

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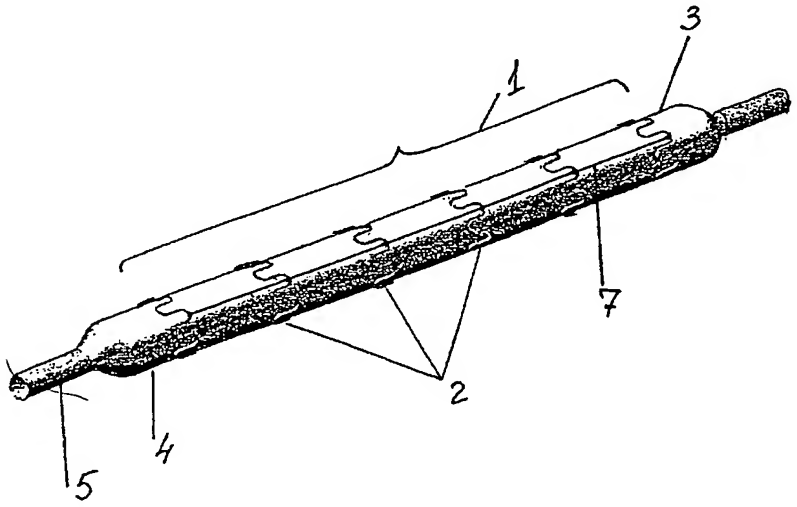

(57) Abstract: Pressure expandable stent for use in a blood vessel or other duct of a human body is provided with a high hoop strength, improved flexibility and minimal adverse effects. The stent includes a plurality of unitary circular members (2, 18, 20, 26) of a generally cylindrical shape made from an appropriate metal alloy and successively arranged along a longitudinal axis of the sent. All or at least a part of the unitary circular members are connected to each other by a single connecting component (7, 76) or by connecting components (71, 72, 73, 74) made of a thin, flexible, non-rigid biocompatible material other than metal. One preferred example of non-rigid biocompatible material is polytetrafluoroethylene. Another group of the preferred materials is constituted by biodegradable polymers. Some of the preferred embodiments of the invention contemplate the use of connecting components in the shape of one or a plurality of threads (7, 73, 75) or thin bands (71, 72, 73). Another preferred embodiment uses as the connecting component a mesh (76) consisting of a plurality of threads (77) of non-rigid biocompatible material, with each thread following a helical path. According to one of the preferred embodiment of the method of manufacture of the stent, producing the string of interconnected circular members includes steps of (a) mounting circular members (18) which are to be connected into one or more strings onto a periphery of a mandrel (40) of essentially cylindrical shape; (b) tightly covering

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said unitary circular members (18) on the mandrel (40) by a detachable cover (60) of an impermeable material, the cover (60) having a through cut (66) or cuts shaped and dimensioned in correspondence to the shape(s) and dimension of one or several of the connecting components to be formed, and (c) applying to unitary circular members (18), through the cut (66) or cuts in the mandrel, (40) a layer of a liquid material which, when solidified, forms the connecting elements of elements.

FLEXIBLE EXPANDABLE STENT AND METHOD FOR MANUFACTURING THE SAME

TECHNICAL FIELD

The present invention relates to pressure expandable endoprostheses, or stent devices for implanting in a body cavity or duct, primarily of the type of tortuous blood vessels and vessel bifurcations, to maintain a patency of the duct and so to allow the flow of fluid therethrough. In another aspect, the present invention relates to manufacture of such stent devices.

PRIOR ART

The stent devices or stents capable upon application of an appropriate external force to expand from a contracted state (characterized by a reduced diameter of the stent) to an expanded state characterized by a diameter greater than or equal to that of the duct wall, are widely used, particularly in treatment of stenosed vessels, arterial aneurysms, biliary tract diseases, etc.

Various types of stents employing various principles of expanding the stent after it is delivered to an appropriate position inside a vessel or another duct have been proposed and employed. One proposed stent type (disclosed, for example, in U.S. Patents Nos. 4,580,568, 4,665,771, 4,733,665) is designed to be disposed, while in compressed or contracted state, about an expandable member such as a balloon on the distal end of a balloon catheter, for subsequent positioning in the desired location within a blood vessel by advancing the catheter through the patient's vascular system. The expandable member is then used to bring the stent into its expanded state by means of inflating the balloon or by applying to the stent an external force of some other kind directed radially outwards, so that a periphery of the stent comes into a contact with walls of the vessel or of another corporal duct being treated and keeps them apart, ensuring patency of the treated vessel. After expansion of the stent is completed, the application of the external force to the stent is stopped (i.e. by deflating the balloon) and the delivery device is withdrawn from the blood system of the patient, leaving the expanded stent within the blood vessel holding open the lumen of the vessel.

The described method of implanting the stents inside a human body and the manner of performing their function of holding open the lumen through the treated vessel defines a rather high and, to a certain degree, contradictory requirements to their mechanical properties. On the one hand, while in the contracted state, the stent must

have a minimal diameter and be flexible, to a rather high degree, so it can be delivered to a required location even through small, bent and tortuous vessels. Further, to minimize a risk of thrombosis and/or other adverse effects for the stented vessel after the implantation (such as intimal hyperplasia), the area of contact between the vessel's walls and metal components of the stent must be minimized. At the same time, when expanded, the stent must display a considerable radial, or "hoop" strength to maintain its expanded shape in the conditions of the complex interaction with a fluid flowing therethrough and especially to withstand substantial radial pressure exerted by walls of the stented duct, which pressure, in addition, can be variable along the length of the stent.

Various prior art stents satisfy all these requirements only to a limited degree. For example, stents composed of metal wire mesh (as described in U.S. Patents Nos. 4,665,771 and 5,575,818 or in Russian patent No. 2,089,131) usually do not possess high radial strength, especially at stent's edges, while stents made as a metal cylinder tube with a plurality of slits in its circumference (as described in U.S. Patents Nos. 4,733,665 and 5,916,264 or EP applications Nos. EP 0,878,174 and EP 0,884,028), or combined from both wire and tube members (as in U.S. Patent No. 5,383,892) are not flexible enough to be inserted into small or tortuous blood vessels.

With object to achieve higher flexibility, it was proposed to make the stent from a plurality of a short closed circular structures (or rings) interconnected by metal (i.e. wire) cross-ties extending generally longitudinally. The cross-ties can be made flexible to change their length in response to a bending force applied to said circular structure (see, for example International Application WO 97/14375 and U.S. Patent No. 5,879,370). However, presence of the cross-ties results in increase of the area of undesirable contact between metal components of the stent and the vessel walls without any desirable increase of the radial strength of the stent.

Furthermore, the process of manufacture of all described prior art stents is rather complicated, which means that the prior art stents are characterized by substantial production costs. These costs are especially high for such special cases as vessel bifurcations. Moreover, complexity of manufacturing process inevitably limits the range of types and sizes of stents available at the market. This circumstance evidently creates certain problems for selecting, in each particular case, the stent, optimal in type and size for a particular patient, taking into account his (or hers) individual peculiarities of the vessel system, character and size of lesion and of other individual factors relevant for an optimal choice of the stent.

It was further proposed (in U.S. Patent No. 5,293,331) to employ low cost stents composed of similar closed unitary circular structures without any interconnections between them. Several such structures are positioned over the balloon portion of the same delivery device for simultaneous expansion after delivery to the affected zone. The main drawbacks of such stents are related to difficulties with precise positioning of non-connected circular members over the balloon of the catheter and to a danger of dislocation of one or several of isolated circular members during the delivery and expansion of the stent inside the vessel or soon after the implantation of the stent, before endothelial growth into the stent will ensure a reliable anchoring of each member in its proper location.

In addition, all commercially available prior art stents have low efficiency when applied for treating vessel bifurcations and arteries in a zone of an ostium of a lateral branch.

DEFINITION OF THE INVENTION

In view of the foregoing, it is the first object of the present invention to provide a stent applicable for implantation inside various body cavities and ducts, including vessels of small diameter, bent or tortuous vessels, bifurcations and vessel ostiums.

It is another object of the present invention to provide a stent having a required high radial strength while exerting a minimal adverse effect on the walls of a body cavity or a duct.

It is the further object of the present invention to provide a relatively simple method for manufacturing a stent intended for a wide range of applications as an implant for various body cavities and ducts, including vessels of small diameter, tortuous vessels, bifurcations and vessel ostiums.

It is still another object of the present invention to provide a simple method for manufacturing a stent, which method can be economically used for optimization of stent's characteristics for a particular patient.

In accordance with the principles of the present invention there are provided a stent and a method for manufacturing this stent.

The stent of the present invention comprises a plurality (at least two) of unitary circular members preferably made from an appropriate metal alloy, such as stainless steel or nitinol, and capable, upon application of a radial force, to expand inside of a body cavity or duct from a contracted to an expanded state and to maintain, while in this expanded state, an open lumen through said cavity or duct. All or at least a part of the unitary

circular members are connected to each other by connecting components or by a single connecting component, as is common the with prior art stents. However, contrary to the prior art stents of this type, the connecting component or components are made not of the same or similar materials as unitary circular members themselves, but of a thin, flexible, non-rigid biocompatible material other than metal.

Preferably, such flexible, non-rigid biocompatible material is selected from the group of biocompatible polymers including polytetrafluoroethylene, polyurethane, polycarbonate urethane, silicone rubber, polyester, polyamide and their combinations.

Some of the preferred embodiments of the invention contemplate the use of connecting components in the shape of one or a plurality of threads, preferably made of polytetrafluoroethylene or other materials, widely used in threads employed in surgical practice. Threads of this type can be obtained, for example, from Gore (Germany) or Ethicon (Johnson and Johnson company, USA). In one of the preferred embodiments a plurality of such threads braided into a mesh in the shape of a cylinder is used. Other embodiments of the present invention employ connecting components in the shape of one or several thin bands.

The method for manufacturing the stent of the present invention comprises a step of producing at least one string of unitary circular members interconnected by at least one flexible non-rigid connecting component. Alternative modifications of this critical step are developed, all of them providing economically viable procedures for connecting unitary circular members into the string. Some of these modifications are simple and flexible enough to be implemented directly in a clinic for the purpose of producing a stent optimized for a particular case of implantation.

The strings of circular members provided by the present invention may include all unitary circular members constituting the stent or, alternatively, the stent may comprise two or more strings non-connected between themselves. In addition, the stent of the invention may include one or several separate unitary circular members non-connected to any string. Easiness and flexibility of connecting unitary circular members by means of flexible non-rigid connecting components provided by the present invention make it possible to include into the stent circular members of practically any shapes and of various dimensions and materials. Owing to this it becomes possible to attain with the stent of the invention a wide range of characteristics desired in different applications, including stenting tortuous and/or small vessels and bifurcations, treating vascular aneurysms, etc.

The use of ring-form circular members provides the stent with a desired high radial strength, which is necessary to conserve its expanded shape for prolonged periods. At the same time, minimization of the area of contact between the vessel's walls and metal members of the stent due to absence of any metal links between these members ensures a ~~very~~ high flexibility of the stent, with no adverse effects, for example, such as thrombosis or intimal hyperplasia. As was shown above, such effects constitute one of the main disadvantages of the prior art stents which include such metal links or are made entirely from a metal cylinder.

In one of the preferred embodiments of the present invention the non-rigid biocompatible material is selected from a group of biodegradable polymers, including polyvalerate, polylactic acid, polyglycolic acid and their combinations. Use of the biodegradable connecting components additionally minimizes potential adverse influence on the vessel inside which the stent is implanted.

These and other objects, advantages and features of the present invention will become more apparent upon considering the following detailed description of preferred embodiments.

BRIEF DESCRIPTION OF THE DRAWINGS

Reference is now made to the drawings of the invention, wherein:

Figure 1 is a simplified perspective view of a plurality of unitary circular members of a stent assembled in a contracted state on the balloon of a delivery system with the aid of a single connecting component;

Figure 2 is a simplified perspective view of the same circular members in an expanded state;

Figure 3 is perspective view, on a larger scale, of the one of the circular members shown in Figs. 1 and 2;

Figure 4 is a simplified perspective view of the same circular members in an expanded state assembled on the balloon of a delivery system with the aid of several connecting components;

Figure 5 is a very schematic presentation of the circular members similar to those shown in Figs. 1 and 2, but positioned at acute angles to the longitudinal axis of the stent;

Figure 6 shows circular members of the stent positioned in a zone of a location of an ostium of a lateral branch;

Figure 7 is a side view of an embodiment of the stent with the connecting component in the form of a mesh;

Figure 8 is a simplified perspective representation of the circular members, shown in the expanded state, of the stent designed for stenting a bifurcation;

Figure 9 is a simplified perspective view, on a larger scale, of some tools used for manufacturing one of the preferred embodiments of the stent according to the present invention.

BEST MODE OF CARRYING OUT THE INVENTION

Fig. 1 illustrates one of the preferred embodiments of the stent 1 according to the present invention. The stent 1 comprises a plurality of unitary circular members 2 (for clarity, only 6 of them are represented). Unitary members of any appropriate configurations employed in the prior art stents or of any other configurations which may be proposed in future may be employed to form the stent 1. The choice of particular configuration(s) evidently is determined by characteristics of a vessel or other body cavity to be stented and by a character of lesion to be treated. An embodiment shown in Fig. 1 uses metal members 2, all of which have the same shape and dimensions.

Unitary circular members 2 are shown in Fig. 1 in their contracted state (corresponding to their minimal diameter). They are placed on a delivery device represented in Fig. 1 by a balloon catheter 3 comprising an angioplastic balloon 4 mounted onto a guide wire 5. Members 2 have no direct contact with each other, that is they are separately arranged along a longitudinal axis O_1-O_1 of the stent 1 (which axis coincides with an axis of the delivery device 3). A distance (or distances) p between adjoining circular members 2 mounted on the delivery device shall be selected with a view to obtain a desired distance (or distances) p' between these members after they will acquire an expanded configuration (shown in Fig. 2) inside a cavity to be treated. Evidently, values of p depend both on a specific task to be solved by the stent and on configuration(s) of employed unitary members. In the majority of the typical cases of employment of the stent 1 p' values will be in the 0,1-15 mm range. For example, when treating residual stenosis, it is recommended to select minimal p' values, while in cases of dissections of the intima much larger p' values should be used.

As can be seen in Figs. 1-3, each member 2 has a generally cylindrical shape. In the context of the present invention the expression "a generally cylindrical shape" means any hollow figure which, when in expanded state, can be mounted, substantially without any clearance, onto a periphery of a circular cylinder. In many practical cases the optimal shape of the members 2 corresponds to a ring 6, that is to a closed three-dimensional unit of a cylindrical shape with an internal diameter at least twice as large as its length.

Preferably each of the rings 6 is made from a single piece of an appropriate metal material (such as a stainless steel or nitinol) and, as shown in Fig. 3, includes several straight portions 8 which are oriented generally parallel to the axis of the stent 1 and connected by curved portions 10. Alternatively, a sinusoidal or any other appropriate shape may be employed, provided it permits to expand the unitary members 2 symmetrically by applying to them a radially, outwardly extending force. As will be evident to persons skilled in the art, the expanded members 2 will have somewhat shorter lengths than when they are in the contracted state, which means that values p' will be somewhat larger than corresponding p values. Because particular configurations of the unitary members used in the present invention do not constitute a part of the present invention and various appropriate configurations of such members are well known to those skilled in the art, a detailed description of these members is not included into the specification. Instead, reference is made to the above-mention patent documents which are included herein by reference.

A distinctive feature of the stent 1 of the present invention is that it comprises one or more connecting components made of a thin, flexible biocompatible material, other than metal. Examples of appropriate materials for use in the connecting components will be given below. The embodiment shown in Figs. 1, 2 comprises only one connecting component 7 shaped as a thread or a very narrow band connecting all unitary circular members 2 into a single string of circular members.

The embodiment of the stent 1 shown in Fig. 4 illustrates flexibility of the present invention in selecting appropriate shape and/or structure of connecting components. According to this embodiment the stent is formed by the unitary circular members 2 of the same type as the above-described embodiment, but, instead of a single connecting component, a plurality of connecting components are used, four of which are shown in Fig. 4. Two of them, namely components 71 and 72 connecting respectively the first (counting from the left) circular member 2 to the second one and the fifth circular member 2 to the last (the sixth) one, are formed as thin bands of an appropriate non-rigid biocompatible material. As can be seen from Fig. 4, end zones of the components 71 and 72 have different shapes, characterized by different areas of contact between these components and corresponding circular members 2. This is done with the purpose to illustrate additional capabilities of the stent according to the present invention for optimization its mechanical characteristics in accordance with various specific tasks.

Each of two other connecting components 73 and 74 is made of the single thread similar to the one shown in Figs. 1 and 2. Again, to illustrate design flexibility of the stent,

the component 73 is shown displaced around the axis of the stent relative to other connecting components, while the connecting component 74 connects three adjacent circular members 2.

One more configuration of the stent 1 comprising at least some of the circular members 20 positioned on the delivery device 3 at an angles different from normal (i.e. selected in the range of 10° to 50°), in relation to the longitudinal axis O_1 - O_1 is very schematically shown in Fig. 5. In other words, an axis O_2 - O_2 of each of such unitary members forms an acute angle α with the axis O_1 - O_1. As can be seen from Fig. 4, different circular members composing the stent 1 may have inclination angles α different not only in value, but also in direction.

As can be seen in Fig. 5, two inclined circular members, 20a and 20b, located in the left part of the stent 1 are connected by the connecting component 71 in the form of a narrow band, similar to that shown in Fig. 4. Connecting component 75, which connects two other inclined circular members, 20c and 20d, is made of two thin threads similar to that designated as 73 in Fig. 4. Thin threads constituting the connecting component 75 are displaced around the axis O_1 - O_1 of the stent relative to each other.

A distinctive feature of this embodiment consists in that two middle circular members, 20b and 20c, are not connected between themselves by any connecting component. As a result, the stent 1 shown in Fig. 5 consists not of a single string (as do stents shown in Figs. 1, 2, 4), but of two separate, non-connected strings 31 and 32.

As schematically illustrated by Fig. 6, the described inclined orientation of at least some of the circular members 26 may be of a specific interest for stenting ostium of a vessel, because the use of such members makes it possible to strengthen a wall W of the affected zone of a vessel V without closing an ostium U of lateral branch B. It can be seen from Fig. 5 and especially from Fig. 6 that in the circular member intended to be mounted at a substantial inclination to the axis of the stent, its straight portions 28 preferably make an acute angle with the axis O_2-O_2 of such member, the value of this angle being approximately equal to the angle α. As a result of taking this measure, when the corresponding unitary member 20, 26 is mounted at a desired angle of inclination to the delivery device 3, the straight segments 28 will be oriented substantially parallel to the axis of the stent, that is at an angle to the axis O_2-O_2 of the member 20.

The connected members illustrated in Figs. 1, 2 and 4 to 6 can be made of any appropriate non-rigid biocompatible material (other than metal), for example of any of materials developed for stent-grafts (described in particular in EP 0,747,069, EP 0,797,963, EP 0,841,040). These materials include, for example, various polymers, such

as polyamide, polycarbonate urethane, polyester, polyolefin, polytetrafluoroethylene, polyurethane, silicone rubber and their co-polymers and combinations.

One of the preferable polymer materials for production of connecting components in accordance with the present invention is polytetrafluoroethylene. Another group of preferred materials is constituted by biodegradable polymers such as polyisobuterate, polyvalerate, polylactic acid, polyglycolic acid and their combinations.

However, the main function of the connecting component(s) according to the present invention is distinctly different from those performed by polymer components in stent-grafts or in stents with unitary circular members made of an appropriate polymer.

More specifically, the connecting component or components 7 serve mainly a purely technological purpose of simplifying the procedure of mounting the plurality of circular members 2 which have no rigid connections between themselves, onto the delivery device 3. Also, connecting components, to a certain degree, prevent displacements of the unitary members relative to each other during the delivery of the stent to the affected body cavity. With the exception of special cases mentioned further in this description, after the stent is expanded and especially after are anchored to the walls of the stented duct as a result of endothelial growth, the connecting component(s) is (are) no more needed. For that reason, there is no necessity to form the connecting component as a sheath typical for the stent-grafts. Moreover, it becomes possible to limit the connecting component(s) to one or several thin threads of the type shown in Fig. 1, 4 and 5, or to one or several narrow bands (of the type shown in Figs. 4 and 5).

For the same reason, in some of the preferred embodiments of the present invention the connecting component(s) is (are) made from one of the appropriate biodegradable materials mentioned above. When the connecting component 7 consists of several bands or threads, these parts of the connecting component preferably are mutually displaced around the longitudinal axis O_1 - O_1 of the stent by an appropriate angle. For example, if the connecting component consists of two bands, their relative displacement preferably equals 180°. However, as shown in Fig. 5, other values of the mutual displacement also can be used.

Fig. 7 illustrates a further embodiment of the stent 1 using circular members made as simple metal rings 18. The main novel feature of this embodiment consists in that the connecting component used therein is formed as a net, or a mesh 76 of a generally cylindrical shape. The mesh 76 is made of a plurality of threads 77 similar to the one shown in Fig. 5, with each thread 77 extending along a helical configuration around the longitudinal axis of the stent. The number of individual threads used for weaving, or

braiding the mesh 76 preferably is selected in the range of 5 to 50 threads, depending mainly on the diameter and configuration of the employed unitary circular members. The connecting component of this type ensures the most reliable and convenient connection between circular members 18 forming a single string 34, while exerting no or minimal pressure on the walls of the stented duct, or cavity.

In addition to circular members shown in Figs 1 to 7, members of many different configurations and sizes can be successfully employed in the stent of the present invention. These configurations include simple rings, hollow cylinders of extended lengths, for example formed by a plurality of mutually interconnected rings (similar to those described with reference to Fig. 1-3) separated form each other in the direction of the axis of the stent. For example, the stent formed by circular members of different diameters is particularly suitable for implantation into a vessel or other duct having a diameter varying along its length. Further, instead of or in combination with the annular members 2, 18, 20 it is possible to use practically any unitary circular members employed in any of prior art stents, including stents of matrix type (known as Palmaz stents). Moreover, the whole stents (including those of Wallsten type) may be included, as unitary circular members, into the stent of the present invention.

An ability to combine, in the single stent, a variety of unitary circular members, substantially different by their physical properties, make it possible to obtain optimal mechanical characteristics for any portion of the stent along its length. For example, it becomes possible to employ matrix members at the ends of the stent (in order to achieve the increased radial strength at this critical portions of the stent), in combination with one or several ring-shaped members in the middle portion of the stent (which make the stent more flexible). The range of characteristics attainable with the stent of the present invention may be additionally broadened by combining unitary circular members connected by the flexible connecting component into a string of circular members, with other members or strings not connected with any other member (as shown in Fig. 5).

Evidently, optimization of stent's parameters along its length can be also achieved by using circular members of the same type, but made from different materials or from the same material but subjected to different type of mechanical and/or thermal treatment. For example, the middle member(s) and the end members of the stent for dealing with residual stenosis can be made of nitinol and of stainless steel, correspondingly.

Finally, the stent of the present invention can be optimized also by varying distances between different pairs of unitary circular components or a pitch of threads

forming the connecting component in the form of the mesh. In some special cases at least one of these distances may be increased up to 20 mm or even to 30 mm.

All described options for optimizing the stent of the present invention can be readily achieved due to a great flexibility of the stent's design combined with a relative easiness of mounting unitary circular members, at least part of which are interconnected by at least one connecting component, onto the delivering device.

Flexibility of the stent design provided by the present invention and its other advantages are illustrated by Fig. 8 which give a perspective view of a next embodiment of the stent designed specially for stenting bifurcations. The stent is shown mounted, in the expanded state, on the delivery device, of which, for purposes of clarity, only guide-wire structure 51 is presented. The embodiment of the stent of Fig. 8 consists of three separate parts, or branches 21, 22, 23 which are not connected between themselves. Each branch 21, 22, 23 is composed by circular members 6_1, 6_2, 6_3 similar in design to circular members 6 of the stent shown in Figs. 1 to 3. However, circular members in each branch have their particular diameters, matched to a diameter of the vessel into which this branch is to be implanted, with the largest circular members being members 6_1 used in the part 21 corresponding to the zone immediately preceding the bifurcation. In the similar manner, the distances between adjoining circular members are made equal along each of the branches 21-23, but they are not equal for all these parts, the largest again being the distances between circular members 6_1 in the part 21.

All circular members 6_1, 6_2 or 6_3 of each branch 21, 22, 23 are interconnected into a single string with the aid of a single connecting component 78 (in the branch 22) or (in the branches 21 and 23) with two connecting components 79 mutually displaced around the periphery of the branch. In addition, the connecting component 78 connects the branches 22 and 23. All connecting components 78, 79 employed in this embodiment of the stent of the present invention are formed as the thin bands similar to those employed in the embodiments of Figs. 4 to 6.

Next, a method for manufacturing the stent according to the present invention will be described, starting with the stent embodiments illustrated by Figs. 1 to 6.

First, a set of unitary circular members, such as 2, 18 or 20 or their combination required to make a particular stent 1 is produced by any of suitable production method well known to those skilled in the art (and disclosed in a number of patents cited above) or by an appropriate combinations of these methods (especially in the case when the stent includes circular members of different configurations and/or of different materials). Then all those members which must be connected into a string are mounted, in the expanded

state, one by one, in the proper order onto a mandrel 40 of a substantially cylindrical shape shown in Fig. 9. For clarity, only two circular members 18 made as a simple metal rings are shown in Fig. 9. The distances between adjoining members are selected to be the same as the required distances between the same members in the implanted stent. A shallow groove 42 is formed in a side surface 44 of the mandrel (for clarity, the depth of the groove in Fig. 9 is strongly exaggerated). A shape and dimensions of the groove 42 in the transverse direction substantially coincide with corresponding parameters of the connecting component to be produced using this particular mandrel. Obviously, the mandrel 40 shown in the Fig. 9 is intended for manufacturing the string of the circular members in form of rings 18, which rings are connected by a thin band generally of the type indicated as 71 or 72 in Figs. 4 and 5. After all rings 18 are mounted to their intended locations, the mandrel 40 is fixed by any suitable means (not shown) in a horizontal position, with the groove 42 open upwards, with its bottom 46 oriented horizontally.

At the next step a special cover 60 is placed over the mandrel 40. As can be seen in Fig. 9, an inner surface of the cover is cylindrical and has a generally complimentary shape to the side surface of the mandrel 60. A number of recesses or cuts 64 are made in the inner surface 62 (only two of them are shown in Fig. 9). These recesses are complimentary in shape to circular members 18 mounted onto the mandrel 40 and their dimensions are made approximately equal to (but slightly larger) than corresponding dimensions of the circular members.

A cut 66 or cuts is (are) made through a side surface 62 of the cover 60. A shape and dimensions of this cut approximately correspond to those of at least one of the connecting components to be formed. It means that a cross-section of the cut in a transverse plane passing through upper edges of the groove 42 (when the cover 60 is placed over the mandrel 40) is similar in shape and has slightly smaller dimensions than those of the groove 42. Either the mandrel 40 or the cover 60 or both are preferably supplied with guiding and latching means (not shown) to place and lock the cover in relation to the mandrel in a position, in which the cut 66 is located in close proximity and directly opposite in radial direction to the groove 42 (that is directly above the groove). Owing to selection of the described shape and dimensions of the cover 60, it can fit very tightly over the mandrel, with no gaps remaining between the inner surface 62 of the cover and the side surface 44 of the mandrel 40. Evidently, with the cover 60 lowered onto the mandrel 40 as described, small upper segments 19 of rings 18 located above the groove 42 will extend through cuts 64.

After the cover 60 is locked in the proper position, the step of connecting circular members 18 mounted onto the mandrel is performed. This step starts with applying a thin layer of an appropriate liquid material through the cut 66 on segments 19 of the rings 18 and on the bottom 46 of the groove 42. By making the width of the cut 66 less than the width of the groove 42 it becomes possible to make a thickness of an applied layer of the liquid material higher than the depth of the groove 42 and in this way to ensure that segments 19 are being covered by the liquid material from all sides.

When the process of applying the layer of the liquid material is completed, this layer is let to solidify. The preferred process of solidification according to the present invention is polymerization. To activate the polymerization and so to cut time needed for solidification, a suitable heat treatment, such as curing of the applied liquid material should be conducted, whenever appropriate. Curing or other suitable heat treatments employed for increasing the rate of polymerization process are well known to persons skilled in the art and amply disclosed in a number of publications. For that reason there is no need to describe them here. Also, standard and well-known equipment for implementing such heat treatment can be employed.

In some cases polymerization can be replaced by using a solution of appropriated polymer with subsequent vaporization of a solvent. For example, solutions of polyolefins in toluene or of silicone rubbers in heptane can be used for this purpose. For producing the biodegradable connecting component 50% polybuterate and 50% polyvalerate dissolved in chloroform may be recommended.

After the material forming the connecting component is solidified, the process of manufacturing the string of interconnected circular members according to the present invention is complete. The cover 60 is unlocked and taken away from the mandrel 40, so that the string of rings 18 connected by the formed thin band of flexible, non-rigid material can be removed from the mandrel 40.

As must be evident to any person skilled in the art, materials for making the circular members, the connecting component, the mandrel and the cover must be selected in such a way that the material of the connecting component has a high adhesion to the material of the circular members (or materials, if they are produced from different materials) and a low adhesion to the materials of the mandrel and the cover. To fulfill this condition, appropriate additional measures can be employed, such as covering with appropriate coating(s) any or some of the mentioned parts in zones open to contact with the material of the connecting component.

Though, for the sake of simplicity, the cover 60 presented in Fig. 9 has only a single cut 66 suitable for production the connecting component in the form of a narrow band, this cover can be supplied with any number of cuts needed to produce a single string of the circular members comprising any suitable connecting component or several components or even two or more separate strings. For example, to produce the string constituting the stent 1 represented in Figs. 1 and 2, a cover with a single narrow slit is needed; while to make the stent of Fig. 4, the cover must have four cuts, two of them being slit-wide, while two other, located at both ends, being similar to the cut 66 shown in Fig. 9. In all cases the grove or groves formed in the mandrel must match, both in shape and dimensions, all cuts made in the cover.

In case one of several cuts formed in the cover are not used in manufacturing a particular modification of the stent, such cut(s) should be preferably covered by appropriate impermeable closure to avoid unintended penetration of the liquid materials through said cut(s).

Evidently, in manufacturing stents employing connecting components of various shapes and dimensions, several appropriate covers can be used in combination with one or several matching mandrels. In case a string similar to the string 32 in Fig. 5 using mutually displaced threads or bands must be produced, the manufacturing process will consist of several steps. Each of steps will be similar to the procedure described above with reference to Fig. 9, and after each step (except the last) is completed, the means fixing the mandrel 40 in a position shall be unlocked and the mandrel shall be turned around its axis by an angle equal to an angle spacing of parts forming the connected component. In this way the next groove 42 will be placed in the upper position suitable for filling. After that the same cover or another cover having a cut of a required shape and dimensions is locked on the mandrel, so that the above-described step of applying a layer of a liquid material can be performed.

To increase productivity, matched pairs of the mandrel and the cover having a large length, suitable for mounting a large number of circular members can be employed. Preferably, but not necessarily, all circular members in this case should have the same shape and dimensions. After the process of connecting each of the mounted circular members with at least one adjoining member by means of one or more connecting components is completed, a string having a required number n ($n \geq 2$) of the circular members can be obtained by cutting or otherwise severing a connecting component connecting unitary circular members numbered n and n + 1 counting from any end of said mandrel. The additional advantage of this approach is that it makes it possible to obtain,

using absolutely the same equipment, strings containing any required number of circular members. On the other hand, the same approach can be employed in production of strings containing a predetermined number of circular members. In this case corresponding sections of the cut or cuts formed in the cover may be closed prior to performing the step of connecting circular members.

As will be evident to persons skilled in the art, instead of the application of the layer of the liquid materials, other, more elaborate methods of manufacturing connecting components from appropriate polymers can be employed, including condensation of a monomer vapor or plasma deposition.

Now two more modifications of the method for manufacturing the string of circular members forming a part of the stent according to the present invention or the whole stent will be briefly described with reference to Fig. 7. The string 34 shown in Fig. 7 employs the connecting component in the form of the mesh 76. Such mesh can be produced by any appropriate method of braiding using a plurality (preferably 5 -50) of threads 77 made from the appropriate flexible material. After the mesh 76 is ready, it is attached to two circular members, such as rings 18, for example, by winding opposite ends of each thread 77 around corresponding ring 18. If the string 34 must include more than two circular members, then another length of the mesh 76 is provided and attached at one end to one of the connected members 18 and at the other end to the next circular member. Using the described method, any number of circular members can be connected into a string, without any limitation to configurations and dimensions of employed circular members. In addition, segments of the mesh 76 connecting different circular members can be made different in length, number of threads, an angle between crossed threads, etc. However, productivity of this method may be limited by the necessity to attach a large number of threads to each of the employed circular members.

More effective in this respect is another modification of the proposed method, according to which all circular members to be connected into a string are attached to the threads of the mesh during the process of braiding the threads into the mesh. This can be done, for example, when employing the following braiding process. First, one end of each thread is attached to a fixed ring-formed holder, with all distances between the ends being equal. The other end of each odd thread and each even thread are then detachably fixed to a first and to a second movable holders, correspondingly. These holders preferably have similar design and are positioned at different distances from the fixed holder along the longitudinal axis of the braiding machine, which axis passes through the center of the fixed holder perpendicularly to the plane of that holder. Both movable holders are made

capable to rotate around this longitudinal axis and to move forward and away from said axis. Initially the movable holders are placed at different distances from said axis, so one of these holders may be considered as an external holder and the other one as an internal holder. Then the external holder performs a stepwise turn around the common axis of the holders. After this rotational step is completed, the holders change their positions relative to their common axis, with the external holder making a step inwards, and the internal holder making a step outwards. That is, the former internal holder becomes the external holder, and vice versa. The described sequence of rotational and rectilinear motions of the holders is then repeated, starting with the step-wise turn of the holder which at the moment is the internal one.

After the appropriate number of rotational steps, corresponding to forming a segment of the mesh 76 of the required length have been completed, the movable holders are stopped, and appropriate circular member, such as the ring 18, is inserted between two groups of threads 77 connected to the external and the internal holders correspondingly, until it butts against joints of the already formed mesh 76. After that the step-wise rotation is resumed, so that the mesh starts to form around the inserted ring 18 firmly holding it in the required position. At the appropriate stage the next ring 18 is inserted, and so on.

Using this method, a very long string 34 can be produced which then can be cut to a number of short strings containing a required number n of circular members.

Another, though much slower method of producing the mesh appropriate for interweaving the circular members into the mesh at the desired locations is disclosed in WO 95/17859. This method allows producing the mesh with any desired number of helical components using a single thread 77 or any desired number of threads.

After the string or all strings required to form a desired stent 1, as well as all separate circular members (if they are employed) are provided, all constituents of the stent are mounted, in the desired order, onto the appropriate delivery device. If the delivery device of the type shown in Figs. 1 and 2 is employed, the circular members, either separate or connected into a string, are mounted onto the balloon 4 of the balloon catheter 3 while being in the expanded state. As was explained above, with reference to Figs. 5 and 6, one or several circular members can be installed in an inclined position relative to the axis of the stent. Employment of one or several strings, instead of separated circular members, substantially facilitates assembling all members on the balloon (especially if the connecting component in form of the mesh is used) in any

required location and/or position, and at the same time ensures maximal flexibility of the stent.

After all circular members are placed into a desired position on the balloon 4, they are fixed to the balloon by the usual procedure of crimping, preferably employing an appropriate tool, such as crimping pliers. The crimping step, which brings the circular members into their radial contracted state, completes the manufacture of the stent according to the present invention, and the stent is now ready to be delivered to the affected duct for implanting therein.

The delivery of the stent of the present invention to the affected duct is performed by transporting the balloon 4 bearing the stent along the guide-wire 5, exactly in the same way as with standard prior art stents, so there is no need in detailed description of this step. However, the high flexibility of the proposed stent and its lower rigidity in the axial direction, due to the absence of any rigid links between the circular members, make it possible to navigate the stent easily through small, bend and/or tortuous pathways to the desired location. At the same time, due to presence of the connecting component or components, the danger of dislocation of any circular member forming a part of the string is substantially less than in the case of employing completely separate, non-connected circular members. This factor is especially important when, with the object of attaining maximum flexibility, very short ring-form members are used.

Implantation of the stent 1 at a desired location consists in a radial expansion of the circular members by inflating the balloon 4 till circular members will come into contact with inner walls of the affected duct. This step is also performed exactly as with the prior art pressure expandable stents. In the initial period after the stent is implanted but before endothelial growth will reliably anchors the circular members to the walls of the vessel or other duct, the connecting component(s) help(s) to prevent (in the same way as metal links between members do in prior art stents) any undesired dislocations of the circular members relative to the vessel. However, in difference to the prior art stents, connecting components of the proposed stent, being flexible, non-rigid and highly compatible with tissues of the stented duct, do not exert any adverse influence on the walls of the duct. This effect is especially pronounced in case the connecting component is made of a biodegradable material. Alternatively, the connecting component or components in the form of band can be employed for a task of prolonged supply of an affected vessel by appropriate substances, such as drugs etc.

Substantially increased flexibility in selecting circular members composing the stent ensures the optimal radial strength of the stent along its entire length, and, what is

also important, by combining in one stent circular members of various configurations, materials and/or dimensions, it becomes possible to meet this condition of optimal strength for a very wide range of types, forms and dimensions of affected ducts, including bifurcations, aneurysms, vessel ostiums, biliary ducts, etc., etc.

Moreover, the final stages of manufacturing the stent of the present invention are so easy and flexible that, especially in unique or urgent cases, the stent can be produced from the available circular members directly in the clinic, according to the specification of a surgeon conducting the stenting operation and employing a procedure described above with reference to Fig. 9. By manufacturing the stent directly in a clinic it becomes possible to take into account all available information regarding a particular patient, for example, a state of his (or hers) vascular system on the whole and of a particular affected vessel, and to optimize all parameters of the stent, including configurations, dimensions and materials of the circular members, distances between them, etc.

Alternatively, when employing stents composed by standard circular unitary members, such as rings 6 or 18 shown in Figs. 2, 7 and 9, there is no need to have at the clinic a supply of stent samples of different lengths, because a stent of any desired length can be easily provided by cutting it from a long string comprising a large number of the circular members.

While particular embodiments of the stent and the method of its manufacturing have been disclosed, it will be appreciated by those skilled in the art that many other modifications could be made to the present invention without deviating from its spirit and scope as so claimed.

Claims

1. A stent for implantation into a body cavity or duct, such as tortuous blood vessel or bifurcation, which stent comprises:

a set of at least two unitary circular members, each member capable to be mounted, while in a contracted state, onto a delivery device to be expanded, upon application of a radially, outwardly extending force, to an expanded state generally in the shape of a hollow cylinder, wherein said unitary circular members, when in expanded state, are separately arranged along a longitudinal axis of the stent; and

at least one connecting component made of a thin, flexible, non-rigid biocompatible material other than metal, for connecting at least two of said unitary circular members to form at least one string of said unitary circular members.

2. The stent of claim 1, characterized in that said non-rigid biocompatible material is biodegradable.

3. The stent of claim 1 or 2, characterized in that said non-rigid biocompatible material is a polymer.

4. The stent of claim 3, characterized in that said polymer is selected from a group consisting of polytetrafluoroethylene, polyurethane, polycarbonate urethane, silicone rubber, polyester, polyamide, polyisobuterate, polyvalerate, polylactic acid, polyglycolic acid and their combinations.

5. The stent of claim 4, characterized in that said polymer is polytetrafluoroethylene.

6. The stent of any of preceding claims, characterized in that it comprises at least three unitary circular members and at least two connecting components, wherein all connecting components are separated form each other in the direction of the longitudinal axis of the stent and wherein each connecting component connects at least two said unitary circular members which are not connected by any other connecting component.

7. The stent of any of claims 1 to 6, characterized in that each of said unitary circular members forms a part of the string of unitary circular members.

8. The stent of any of preceding claims, characterized in that at least one connecting component is formed by a single thread of said non-rigid biocompatible material.

9. The stent of any of claims 1 to 7, characterized in that at least one connecting component is formed by at least two threads of said non-rigid biocompatible material displaced around the longitudinal axis of the stent relative to each other.

10. The stent of any of claims 1 to 7, characterized in that at least one connecting component is formed as a band of said non-rigid biocompatible material.

11. The stent of any of claims 1 to 7, characterized in that at least one connecting component is formed as at least two bands of said non-rigid biocompatible material displaced around the longitudinal axis of the stent relative to each other.

12. The stent of any of claims 1 to 7, characterized in that it comprises at least one connecting component formed as at least one thread of said non-rigid biocompatible material and at least one connecting component formed as a band of said non-rigid biocompatible material.

13. The stent of any of claims 1 to 7, characterized in that at least one connecting component is formed as a braided mesh extending over external periphery of the unitary circular members connected by said connecting component.

14. The stent of claim 1, characterized in that at least one of the unitary circular members is shaped as a ring, which ring, in its expanded state, has a diameter at least twice exceeding its length.

15. The stent of any of preceding claims, characterized in that, when the stent is in its extending state, a distance between adjacent unitary circular members corresponds to 0,1 - 15 mm.

16. The stent of claim 1, characterized in that, when the stent is in its extending state, a distance between a pair of adjacent unitary circular members differs from the distance between adjacent unitary circular members of at least one other pair of adjacent unitary circular members.

17. The stent of any of preceding claims, characterized in that at least two of unitary circular members, when in their expanded states, have substantially different external diameters.

18. The stent of any of preceding claims, characterized in that at least two of unitary circular members, when in their expanded states, have substantially different spatial configurations.

19. The stent of any of preceding claims, characterized in that, when the stent is in its expanded state, an axis of at least one of said ring-shaped unitary circular members forms with a longitudinal axis of the stent an angle different from 90°, preferably the angle selected in a range of 10° to 50°.

20. The stent of claim 19, characterized in that, when the stent is in its expanded state, the axes of at least two of said ring-shaped unitary circular members form substantially different angles with a longitudinal axis of the stent

21. The stent of any of preceding claims, characterized in that all unitary circular members are connected by the single connecting component.

22. The stent of any of claims 1 to 20, characterized in that it consists of three separate parts, each part capable to be mounted, while in a contracted state, onto one leg of the delivery device designed for stenting a vessel bifurcation.

23. A method for manufacturing a stent, which method comprises the following steps:

providing a set of at least two unitary circular members, each member capable to be mounted, while in a contracted state, onto a delivery device to be expanded, upon application of a radially, outwardly extending force, to form in the expanded state a configuration generally in the form of a hollow cylinder;

producing at least one string of said unitary circular members comprising n unitary circular members, wherein $n \geq 2$, connected to each other by means of at least one connecting component made of a thin, flexible, non-rigid biocompatible material other than metal;

mounting all unitary circular members of said set of the unitary circular members onto a delivery device wherein said unitary circular members are separated form each other in the direction of an longitudinal axis of the stent to be arranged, when in expanded state, along a longitudinal axis of the stent;

if any of said unitary circular members are mounted onto said delivery device while being in the expanded state, bringing all such unitary circular members into a contracted state.

24. The method of claim 23, characterized in that at least one string of said unitary circular members is made by connecting at least three of said unitary circular members by means of at least two of said connecting components, wherein all connecting components are separated form each other in the direction of the longitudinal axis of the stent and wherein each connecting component connects at least two said unitary circular members which are not connected by any other connecting component.

25. The method of claim 23 or 24, characterized in that the step of producing at least one string of said unitary circular members comprises the following steps:

mounting onto a periphery of a mandrel of essentially cylindrical shape all those unitary circular members from said set of unitary circular members which are to be connected into one or more strings, wherein said unitary circular members are mounted in the expanded state and in the order and relative positions

corresponding to the desired order and relative positions of said unitary circular members at the stage of implantation the stent into the said duct;

applying a thin layer of a liquid material to at least one segment of each of said unitary circular members to a periphery of said mandrel located between said unitary circular members to be connected into the string, which material is capable to solidify into said flexible, non-rigid biocompatible material;

letting said layer of the liquid material to solidify; and

after said layer has been solidified, detaching said unitary circular members, connected by one or more of said connected components, into one or more strings of unitary circular members, from said mandrel.

26. The method of claim 23, characterized in that said step of producing at least one string of said unitary circular members comprises the following steps:

mounting onto a periphery of a mandrel of essentially cylindrical shape a plurality of said unitary circular members in an extended state, which circular members are separated form each other in the direction parallel to the longitudinal axis of the stent;

connecting all said unitary circular members by means of at least one connecting component;

severing a connecting component connecting unitary circular members numbered n and n + 1 counting from any end of said mandrel; and

detaching said string of n unitary circular members from said end of said mandrel.

27. The method of claim 25 or 26, characterized in that said solidifying step comprises curing.

28. The method of any of claims 23 to 27, characterized in that at least one connecting component is formed as a thread of said non-rigid biocompatible material.

29. The method of any of claims 23 to 27, characterized in that at least one connecting component is formed as at least two threads of said non-rigid biocompatible material displaced around the longitudinal axis of the stent relative to each other.

30. The method of any of claims 23 to 27, characterized in that at least one connecting component is formed as a band of said non-rigid biocompatible material.

31. The method of any of claims 23 to 27, characterized in that at least one connecting component is formed as at least two bands of said non-rigid biocompatible material displaced around the longitudinal axis of the stent relative to each other.

32. The method of any of claims 26 to 28, characterized in that said mandrel has at least one shallow groove extending along its periphery, wherein

a shape and dimensions of said groove in the transverse direction substantially coincide with a shape and dimensions in the transverse direction of at least one of said connecting components;

said step of applying said layer of the liquid material is preceded by a step of tightly covering said unitary circular members mounted onto the mandrel by a detachable cover of an impermeable material, wherein the cover has a through cut or cuts shaped and dimensioned approximately in correspondence to the shape(s) and dimensions of at least one of the connecting components to be formed;

said cover is positioned over the mandrel in such a way that said cut or cuts are located in close proximity and directly opposite in a radial direction to said groove or grooves made in the side surface of the mandrel; and

said step of applying the thin layer of the liquid material is performed by applying said liquid materials through said cut or cuts in said cover, which cover is detached from the unitary circular member after said step of applying is completed.

33. The method of any of claims 26 to 28, characterized in that at least one connecting component is formed as a braided mesh extending over external periphery of the unitary circular members connected by said connecting component into the string.

34. The method of claim 33, characterized in that at least one connecting component in the form as the braided mesh is manufactured by braiding a plurality of components of said mesh using a single thread or a plurality of threads, wherein all unitary circular components connected by said connecting component are attached to said component by braiding the threads of the mesh around the unitary circular components in the process of manufacturing said connecting component.

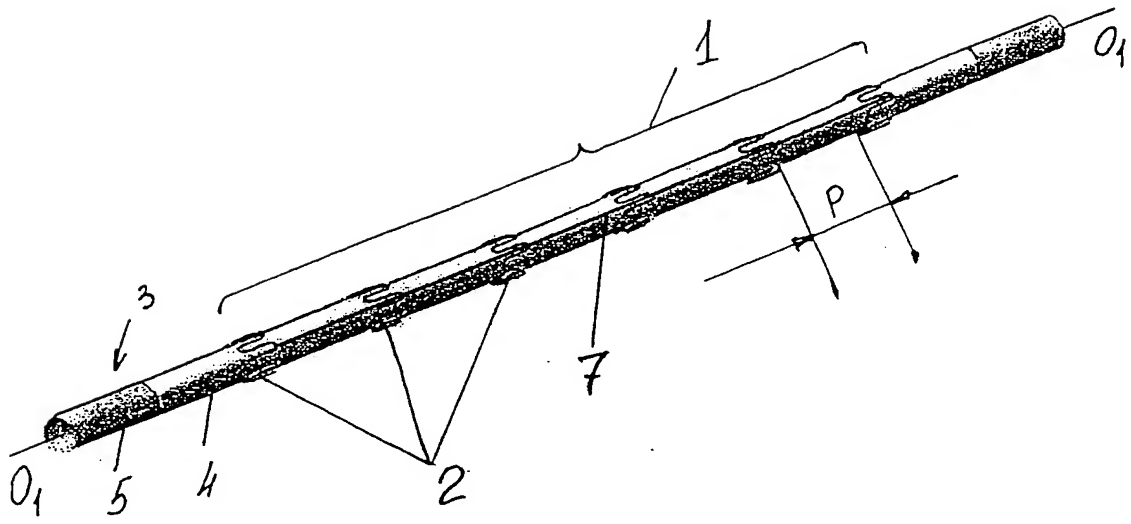

Fig. 1

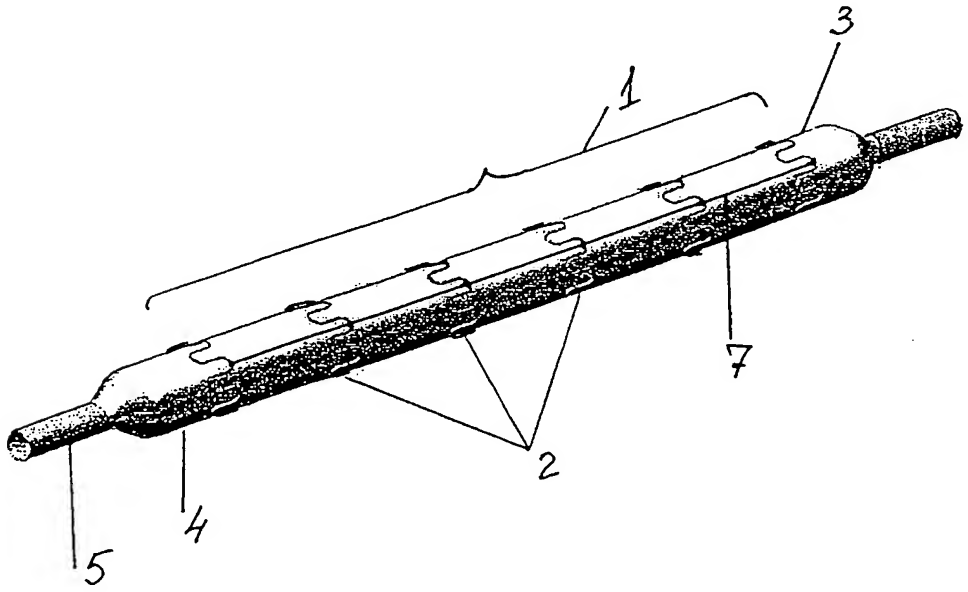

Fig. 2

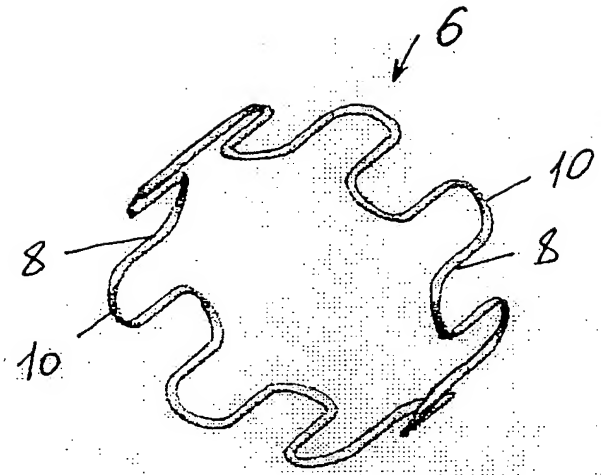

Fig. 3

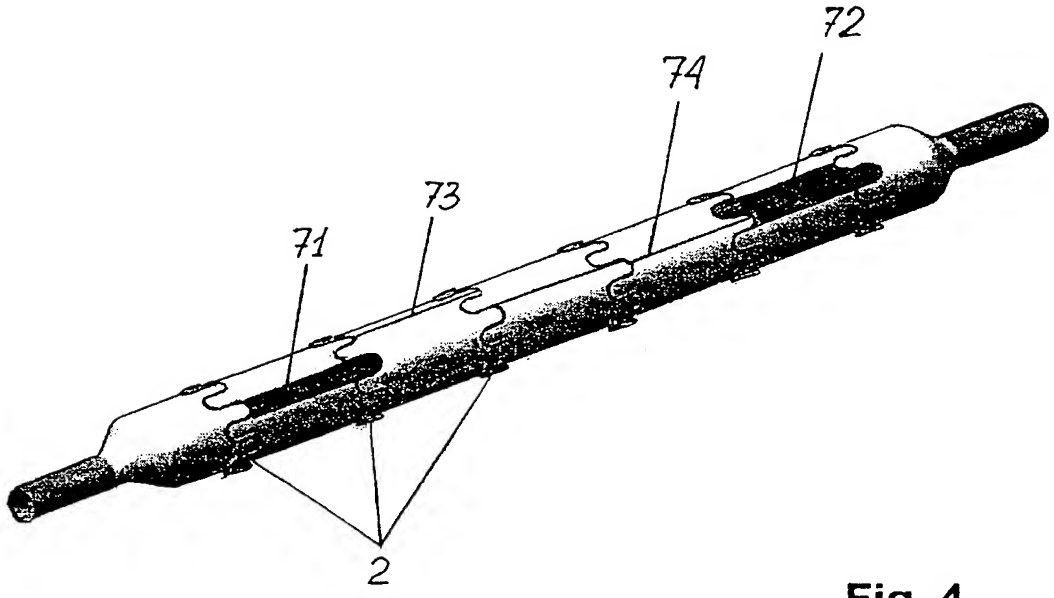

Fig. 4

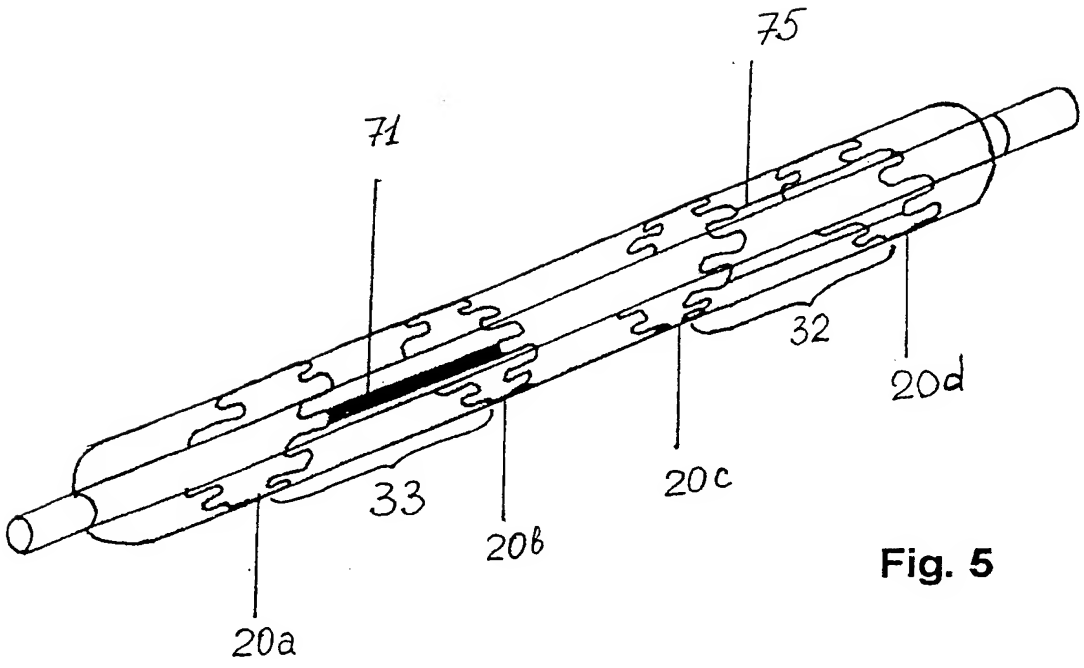

Fig. 5

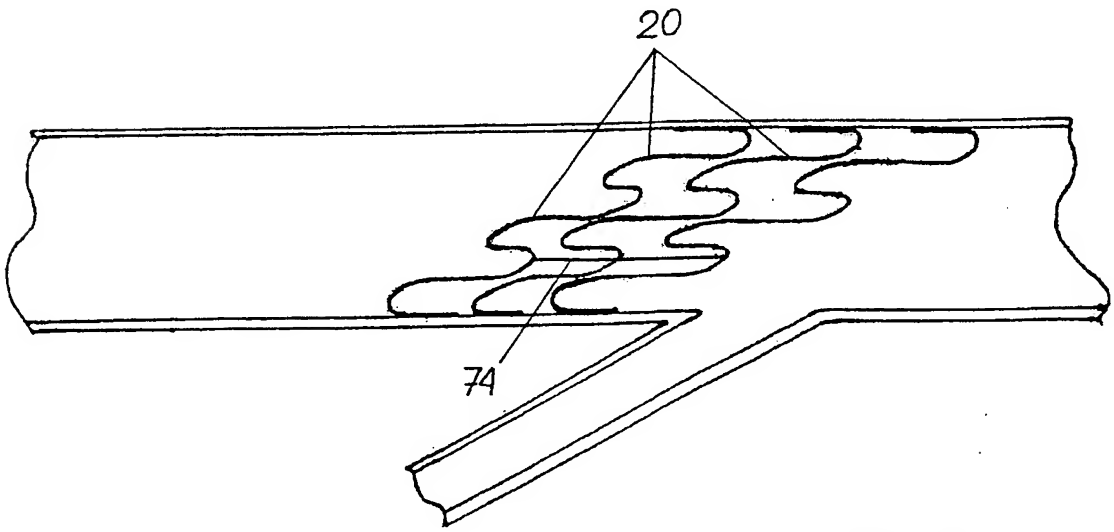

Fig. 6

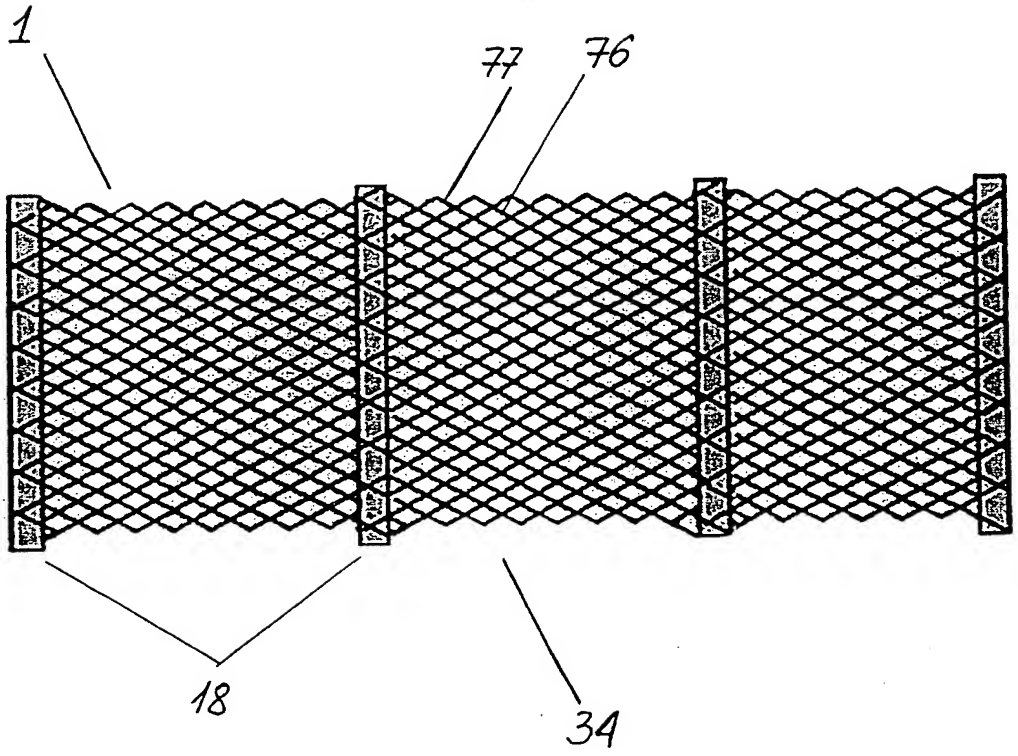

Fig. 7

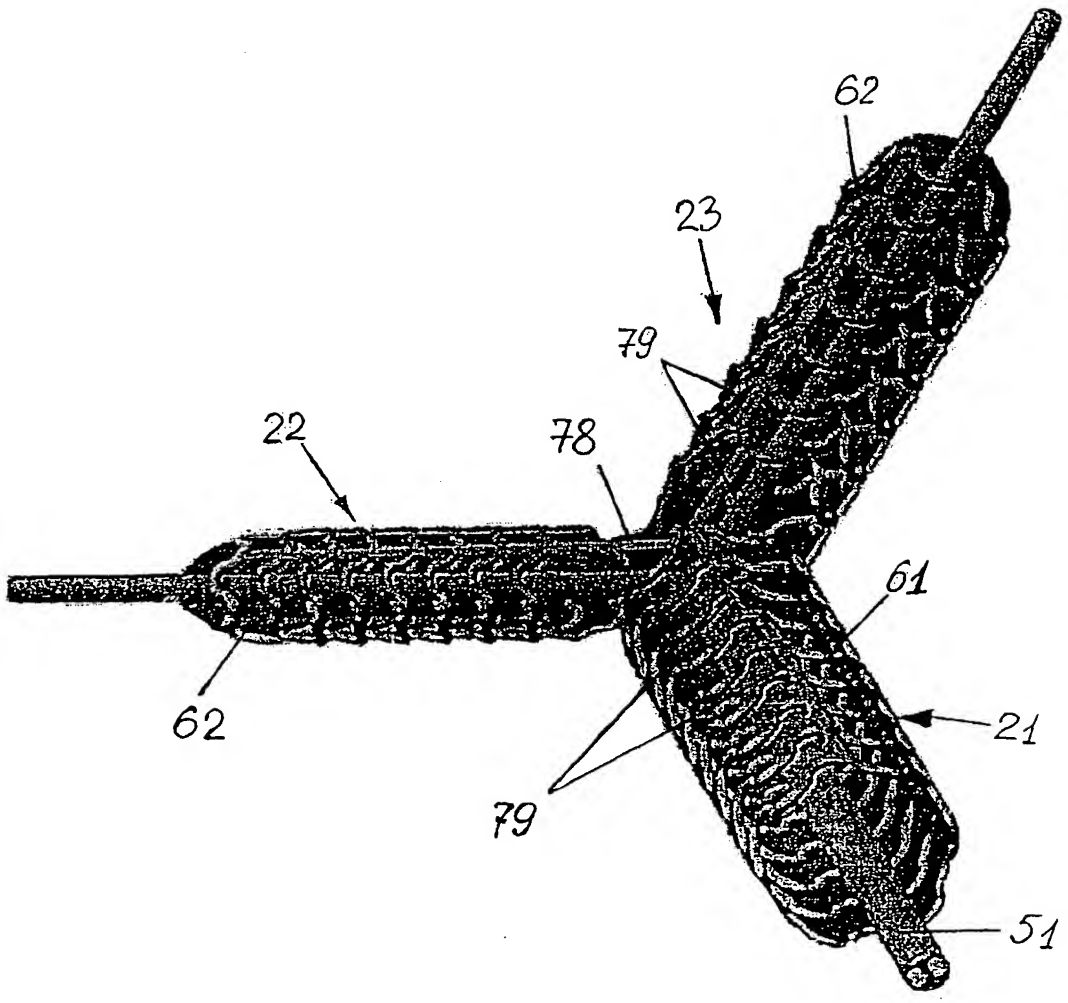

Fig. 8

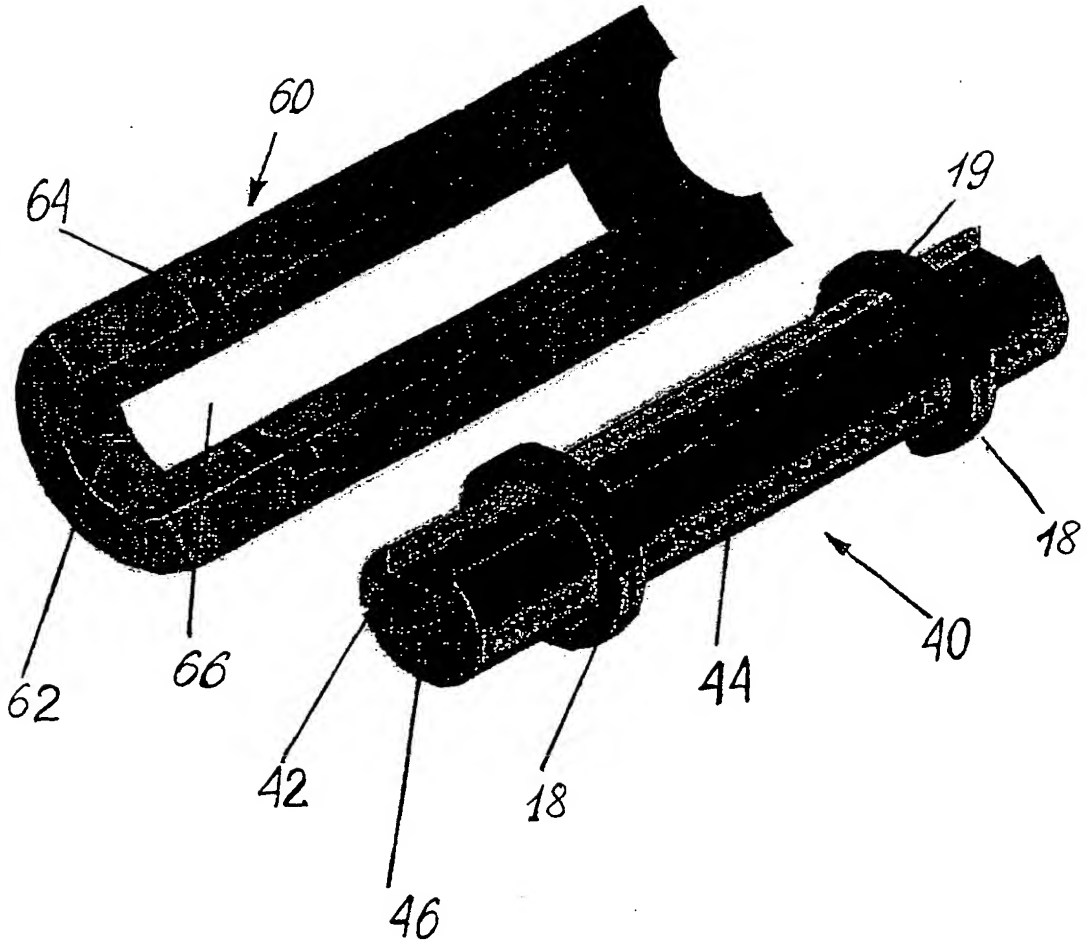

Fig. 9

INTERNATIONAL SEARCH REPORT

International Application No
PCT/RU 00/00374

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
WPI Data, EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 98 20810 A (MEDTRONIC, INC.) 22 May 1998 (1998-05-22)	1,3-10, 14,19, 23,24, 28-30
Y	page 22, line 6 -page 23, line 35; figures ---	2
Y	EP 0 634 152 A (VIHERKOSKI) 18 January 1995 (1995-01-18) claim 1 ---	2
X	WO 97 37617 A (JAYARAMAN) 16 October 1997 (1997-10-16) the whole document --- -/--	1,3-9, 23,24, 28,29

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
2 March 2001	08/03/2001

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Smith, C

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Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

national Application No
PCT/RU 00/00374

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 851 228 A (PINHEIRO) 22 December 1998 (1998-12-22) the whole document _____	1,3,7-9, 21-23, 28,29

1

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9820810 A	22-05-1998	NONE	
EP 634152 A	18-01-1995	FI 932752 A	16-12-1994
		FI 942170 A	16-12-1994
		FI 942531 A	16-12-1994
WO 9737617 A	16-10-1997	US 5725548 A	10-03-1998
		US 5713949 A	03-02-1998
		AU 729119 B	25-01-2001
		AU 2728097 A	29-10-1997
		CA 2250954 A	16-10-1997
		EP 1006938 A	14-06-2000
		US 5755781 A	26-05-1998
		US 5895407 A	20-04-1999
		US 5922393 A	13-07-1999
US 5851228 A	22-12-1998	AU 711503 B	14-10-1999
		AU 5959896 A	18-12-1996
		CA 2223829 A	05-12-1996
		EP 0831753 A	01-04-1998
		JP 10510200 T	06-10-1998
		WO 9638101 A	05-12-1996